

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/12/08 has been entered. MPEP 7.42.04

### ***Amendment***

2. The amendment filed on 8/12/08 is acknowledged and entered.

### ***Status of claims***

3. Claims 1-37, 39 and 44-45 are cancelled.  
Claims 38, 40-43, and 46-62 have been amended.  
New Claims 61-62 have been added.  
Claims 38, 40-43, and 46-62 are pending.  
Claims 51-52 and 55-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions M.P.E.P. § 821.03.  
Claims 38, 40-43, 46-50, 53-54 and 61-62 are drawn to the elected invention and are under examination.  
The examiner has withdrawn all the rejections of record and issuing a new Office action in view of submission of RCE.

### ***Claim Rejections - 35 USC 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 38, 40-43, 46-50 and 53-54 rejected under 35 U.S.C. 103(a) as being unpatentable over Doucette-Stamm et al U.S. Patent No. 6,380,370.

Claims are drawn to a pharmaceutical composition comprising an isolated hyper immune serum reactive antigen *S.epidermidis* hyper immune serum reactive antigen SEQ ID NO. 32 or fragments thereof and optionally a pharmaceutically-acceptable carrier or excipient said pharmaceutical composition further comprising an immunostimulatory substance.

Doucette-Stamm et al teach an isolated hyper antigen comprising the amino acid sequence SEQ.ID.NO: 4318 (i.e., fragment) and is 98.7 % identical to the claimed SEQ.ID.NO: 32 (see the sequence alignment).

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US-09-134-001C-4318
Sequence 4318, Application US/09134001C
Patent No. 6380370
US-09-134-001C-4318

Query Match          98.7%; Score 3325; DB 2; Length 676;
Best Local Similarity 99.0%; Pred. No. 1e-214;
Matches 669; Conservative 0; Mismatches 7; Indels 0; Gaps 0;

Qy      1 MKRTDKIGVYLKSCSALLSGSLVGYGPTKDAFADSESTSSNVENTSNSNSIADKIQQA 60
      |||
Db      1 MKRTDKIGVYLKSCSALLSGSLVGYGPTKDAFADSESTSSNVENTSNSNSIADKIQQA 60

Qy      61 KDDIKDLKELSDADIKSFEERLDKVDNQSSIDRIINDAKDKNNHLKSTDSSATSSKTEDD 120
      |||
Db      61 KDDIKDLKELSDADIKSFEERLDKVDNQSSIDRIINDAKDKNNHLKSTDSSATSSKTEDD 120

Qy      121 DTSEKNDMDMTKDLKILSDLSIAKNVQNGEERASKPSDSTTDEKDDSNKVVHDTN 180
      |||
Db      121 DTSEKNDMDMTKDLKILSDLSIAKNVQNGEERASKPSDSTTDEKDDSNKVVHDTN 180

Qy      181 ASTRNAATTDSEESVIDKLKIQDQFKSDSNNNPSEQSDQOASPSNKTENNKEESSTTTN 240
      |||
Db      181 ASTRNAATTDSEESVIDKLKIQDQFKSDSNNKLSQSDQOASPSNKNENNKEESSTTTN 240

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Qy	241	QSDSDSKDDKSNNGHRSTLERIASDTDDQIRDSKDQHVTDEKQDIQAITRSLQGSCKIEKA	300
Db	241	QSDSDSKDDKSNNGRRSTLERIASDTDDQIRDSKDQHVTDEKQDIQAITRSLQGSCKIEKA	300
Qy	301	LAKVQSDNQSLDSNYINNKLMNLSLDTKVEDNNTLSDDKKQALKQEI DKTQSIDRQRN	360
Db	301	LAKVQSDNQPLDSNYINNKLMNLSLDTKVEDNNTLSDDKKQALKQEI DKTQSIDRQRN	360
Qy	361	IIIDQINGASNNKQATEDIILNSVFSKNEVEDIMKRIKTNGRGNEDIANQIAKQIDGLALT	420
Db	361	IIIDQINGASNNKQATEDIILNSVFSKNEVEDIMKRIKTNGRGNEDIANQIAKQIDGLALT	420
Qy	421	SSDDILKGMLDQSKDKESLIKQLLTTRLGNDEADRIAKKLLSQNLNSQIVBQLKRHPNS	480
Db	421	SSDDILKGMLDQSKDKESLIKQLLTTRLGNDEADRIAKKLLSQNLNSQIVBQLKRHPNS	480
Qy	481	QGTATADDIILNGVINDAKDKRQAIETILQTRINKDKAKI IADVIARVQDKSDIMDLIHS	540
Db	481	QGTATADDIILNGVINDAKDKRQAIETILQTRINKDKAKI IADVIARVQDKSDIMDLIHS	540
Qy	541	AIEGKANLLDIEKRAKQAKKOLEYILDPIKNRPSLLDRINKGVGDSNSIFDRPSLLDKL	600
Db	541	AIEGKANLLDIEKRAKQAKKOLEYILDPIKNRPSLLDRINKGVGDSNSIFDRPSLLDKL	600
Qy	601	HSRGSILDKLHSAFENGLSLDNKGGLSDFDDGNGISLPATGEVIKQHWIPVAVVLMS	660
Db	601	HSRGSILDKLHSAFENGLSLDNKGGLSDFDDGNGISLPATGEVIKQHWIPVAVVLMS	660
Qy	661	LGGALIFMARRKKHQ N	676
Db	661	LGGALIFMARRKKHQ N	676

The art teaches that the antigen SEQ.ID.NO: 4318 (see is reactive to serum antibodies (see column 40). The antigen comprises fragments ranging from 5 or more amino acids. The teaching of the Patent No. 6380370 indicate that the composition comprises *S.epidermidis* antigen or peptide fragment SEQ.ID.NO: 4318 (see columns 37 –38) in a pharmaceutically acceptable carrier or an adjuvants etc (see columns 37 –38). The composition comprises two different hyper immune serum reactive antigens as 676 amino acid sequence comprises different fragments. As the antigen has more than 10 amino acids it is immunogenic because it is known in the art of immunology that peptides as few as at least five amino acids induce an antibody that is used for identifying epitopes of a given antigen.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the composition comprising the antigen or it s fragments as a pharmaceutical composition because the antigen is obtained from *S.epidermidis* and the art suggests it reacts to antibodies and can be used for diagnosis of *S.epidermidis* infection. The claimed invention is prima facie obvious in view of Doucette-Stamm et al absent any convincing evidence to the contrary.

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8. Claims 38, 40-43, 46-50 and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimmerly WJ, AAG81977, WO200134809-A2.

Claims have been discussed supra in Paragraph # 7

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AG81977
ID   AAG81977 standard; protein; 356 AA.
XX
AC   AAG81977;
XX
DT   03-SEP-2001 (first entry)
XX
DE   S. epidermidis open reading frame protein sequence SEQ ID NO:1048.
XX
KW   Staphylococcus epidermidis SR1 strain; infection; diagnosis; vaccination;
KW   endocarditis.
XX
OS   Staphylococcus epidermidis.
XX
PN   WO200134809-A2.
SQ   Sequence 356 AA;

Query Match      52.4%; Score 1765; DB 4; Length 356;
Best Local Similarity 100.0%; Pred. No. 1.7e-87;
Matches 356; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      321  MNLRLSDTKVEDNNTLSDDKKQALKQEIDKTKQSIDRQRNIIIDQLNGASNKKQATEDIL 380
      |||
Db      1  MNLRLSDTKVEDNNTLSDDKKQALKQEIDKTKQSIDRQRNIIIDQLNGASNKKQATEDIL 60

Qy      381  NSVFSKNEVEDIMKRKTNGRSNEDIANQIAKQIDGLALTSSDDILKSMGLDQSKDKESLI 440
      |||
Db      61  NSVFSKNEVEDIMKRKTNGRSNEDIANQIAKQIDGLALTSSDDILKSMGLDQSKDKESLI 120

Qy      441  KQLLTTRLGNDEADRIAKKLLSQNLNSQIVQLKRRHPNSQGTATADDILNGVINDAKDK 500
      |||
Db      121 KQLLTTRLGNDEADRIAKKLLSQNLNSQIVQLKRRHPNSQGTATADDILNGVINDAKDK 180

Qy      501  RQAETILQTRINKDKAKIIADVIARVQKDKSDIMDLIHSAGKANDLLDIEKRAKQAK 560
      |||
Db      181 RQAETILQTRINKDKAKIIADVIARVQKDKSDIMDLIHSAGKANDLLDIEKRAKQAK 240

Qy      561  KDLEYILDPIKRNPSLLDRINKGVGDSNSIFDRPSLLDKLHSGSILDKLDHAPENGLS 620
      |||
Db      241 KDLEYILDPIKRNPSLLDRINKGVGDSNSIFDRPSLLDKLHSGSILDKLDHAPENGLS 300

Qy      621  LDNKGGLSDFDDGDNISLPATGEVIKQHWIPVAVVIMSLGALIFMARKKHQN 676
      |||
Db      301 LDNKGGLSDFDDGDNISLPATGEVIKQHWIPVAVVIMSLGALIFMARKKHQN 356

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Kimmerly WJ teaches an antigen comprising (i.e., fragment) fragment and said fragment is 52.4% identical to the claimed hyper immune serum reactive antigen *S. epidermidis* antigen comprising fragments thereof (see the sequence alignment). The antigen comprises fragments ranging from 5 or more amino acids. The teachings of the prior art indicate that the composition comprises *S. epidermidis* antigen or peptide fragment in a pharmaceutically acceptable carrier or an adjuvants etc (pages 33-35 of patent). The composition comprises two different hyper immune serum reactive antigen as it is a 356 amino acid sequence. As the antigen has more

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than 10 amino acids it is immunogenic because it is known in the art of immunology that peptides as few as at least five amino acids induce an antibody that is used for identifying epitopes of a given antigen.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the composition comprising the antigen or its fragments as a pharmaceutical composition because the antigen is obtained from *S.epidermidis* and the art suggests it reacts to antibodies and can be used for diagnosis of *S.epidermidis* infection. The claimed invention is prima facie obvious in view of Doucette-Stamm et al absent any convincing evidence to the contrary.

Applicant's arguments submitted on 8/12/08 (pages 7-10) drawn to the previous rejection of then pending claims are relevant to the instant rejection.

### ***Conclusion***

9. Claims 61-62 are free of prior art and are allowable.

Claims 38, 40-43, 46-50 and 53-54 are rejected.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 156, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571) 272-0956.

Respectfully,

/Padma V Baskar/

Examiner, Art Unit 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645